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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,316	01/23/2004	Michael J. Borrelli	10546-109	8323

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EXAMINER	
CHONG, KIMBERLY	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,316	BORRELLI, MICHAEL J.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-5 and 8-13, drawn to a gene therapy vector comprising a first polynucleotide encoding *H. ducreyi* cdtB gene and a second polynucleotide encoding an antisense oligonucleotide that inhibits expression of a sense polynucleotide encoding a DNA repair protein, classifiable in class 536, subclass 24.5. This group is subject to a further species election.

II. Claims 2-5 and 8-13, drawn to a gene therapy vector comprising a first polynucleotide encoding *C. jejuni* cdtB gene and a second polynucleotide encoding an antisense oligonucleotide that inhibits expression of a sense polynucleotide encoding a DNA repair protein, classifiable in class 536, subclass 24.5. This group is subject to a further species election.

III. Claims 2-13, drawn to a gene therapy vector comprising a first polynucleotide encoding *E.coli* cdtB gene, having SEQ ID NO. 5, and a second polynucleotide encoding an antisense oligonucleotide that inhibits expression of a sense polynucleotide encoding a DNA repair protein,

classifiable in class 536, subclass 24.5. This group is subject to a further species election.

IV. Claims 14-17, drawn to an adenoviral vector for performing cytolethal gene therapy comprising a first polynucleotide encoding cdtB gene, a second nucleotide sequence encoding an antisense oligonucleotide that inhibits expression of ku70 and a heat shock promoter, classifiable in class 536, subclass 24.5.

V. Claims 18-31, drawn to a method of conducting cytolethal gene therapy comprising providing a vector comprising a first polynucleotide encoding a gene for a B subunit of a cytolethal distending toxin, a second polynucleotide encoding an antisense oligonucleotide that inhibits expression of a sense oligonucleotide encoding a DNA repair protein and a heat shock promoter and delivering the vector to the desired cell, classifiable in class 514, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions groups I, II and III are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have

different designs. For example, group I is drawn to a gene therapy vector comprising a first polynucleotide encoding a *H. ducreyi* cdtB gene, which is materially different than the gene therapy vector of group II comprising a first polynucleotide encoding a *C. jejuni* cdtB gene. Further, group I and II are materially different than the invention of group III drawn to a gene therapy vector comprising a first polynucleotide encoding *E.coli* cdtB gene. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions groups I-III and group IV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different designs and different modes of operation. For example, groups I-III are drawn to a gene therapy vector which encompasses vectors other than the adenoviral vector of group IV and further the vectors from groups I-III and group IV have different modes of operations. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for an adenoviral vector would not necessarily reveal art against all the types of vectors encompassed in groups I-III. It is therefore a burden to search these inventions in a single application.

Inventions groups I-IV and group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of conducting cytolethal gene therapy can be practiced using naked DNA, which is materially different than a gene therapy vector comprising a first polynucleotide and a second polynucleotide operably linked to a promoter.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 11 and 12 are directed to the following patentably distinct species of the claimed invention of gene therapy vectors: plasmids, phages, phagemids, viruses and artificial vectors. Each of the claimed gene therapy vectors would infect the cell differently and express different amounts of from the first polynucleotide and seconding polynucleotides in the cells.

Additionally, if applicant elects viral vectors from either of groups I, II or III, applicant is required to further elect a single disclosed species of viral vectors. Claim 13 is directed to the following patentable distinct species of viral vectors: papovirus, lentivirus, adenovirus, vaccinia virus, adeno-associated virus, herpes virus and retrovirus. Each of the claimed viral vectors would bind to different receptors on the cell and infect the cell at different rates.

Further, claim 24 is directed to the following patentable distinct species of viral vectors used in claimed invention of a method of conducting cytolethal gene therapy: papovirus, lentivirus, adenovirus, vaccinia virus, adeno-associated virus, herpes virus and retrovirus. Each of the claimed viral vectors would bind to different receptors on the cell and infect the cell at different rates

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of gene therapy vectors from claims 11 and 12 and if applicant elects viral vectors, applicant is required to elect a single disclosed species of viral vectors for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic for gene therapy vectors.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim 1 link(s) inventions groups I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635

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1635